510(K) SUMMARY

Newdeal TIBIAXYS System

Submitter's name and address:

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Contact person and telephone number

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Date Summary was prepared:

November 30, 2007

Name of the device:

Proprietary Name:	Newdeal TIBIAXYS System
Common Name:	Plate, Fixation, Bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories (21CFR 888.3030)
Device Product Code:	HRS
Classification Panel:	Orthopedic

Substantial Equivalence:

The Newdeal TIBIAXYS System includes three types of plates. The plates include: 1) Anterior plates, 2) Medial or Lateral plates and 3) Fibula plates.

Anterior Plates are substantially equivalent to the Synthes Ankle Arthrodesis Plate, K022255, the Newdeal TTC Plates, K060473.

Medial and Lateral Plates are substantially equivalent to the Acumed Lower Extremity Congruent Plate System, K033639.

Fibula Plates are substantially equivalent to the Acumed Lower Extremity Congruent Plate System, K033639.

Device Description:

The Newdeal TIBIAXYS System consists of bone plates and screws for arthrodesis, osteotomies and fractures of ankle joint, distal tibia and fibula. All plates and screws are manufactured from titanium alloy and are provided either sterile or non-sterile.

Intended Use:

The Newdeal TIBIAXYS System is indicated for fixation of bone fractures or for bone reconstruction including Arthrodesis, Osteotomies and fractures of ankle joint, distal tibia and fibula.

The Newdeal TIBIAXYS Plates have to be fixed with the SURFIX and SURFIX ALPHA 3.5mm diameter Locking System (screws and Lock screws).

Anterior plates for ankle Arthrodesis have to be fixed with the TIBIAXYS 4.0mm diameter cortical screws.

Testing and Test Results:

TIBIAXYS System was tested and compared to the expected *in vivo* performance and to the predicate devices.

All the results show that the Newdeal TIBIAXYS System has mechanical properties compatible with their intended uses.

Conclusion

The Newdeal TIBIAXYS System are substantially equivalent to predicate device.

The TIBIAXYS *Anterior Plate* is substantially equivalent to the Synthes Ankle Arthrodesis Plate, K022255, and the Newdeal TTC Plates, K060473.

The TIBIAXYS *Medial and Lateral Plates and Fibula Plate* are substantially equivalent to the Acumed Lower Extremity Congruent Plate System, K033639.

The Newdeal TIBIAXYS System does not raise any new issues of scientific technology, safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

Newdeal SAS
% Ms. Judith O'Grady
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536

Re: K073375
Trade/Device Name: Newdeal TIBIAXYS System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: November 30, 2007
Received: December 3, 2007

Dear Ms. O'Grady:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K073375

Device Name: Newdeal TIBIAXYS System

Indications For Use :

The Newdeal TIBIAXYS System is indicated for fixation of bone fractures or for bone reconstruction, including Arthrodesis, Osteotomies and fractures of ankle joint, distal tibia and fibula.

The Newdeal TIBIAXYS Plates are fixed with the SURFIX and SURFIX ALPHA Locking System 3.5mm diameter screws and Lock screws. Anterior Plates for ankle Arthrodesis have to be fixed with the TIBIAXYS cortical 4mm diameter screws.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073375